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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,680	09/19/2001	Michael J. O'Neil	101896-0031	1266
21125 7590 05/13/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
HOFFMAN, MARY C				
ART UNIT		PAPER NUMBER		
3733				
NOTIFICATION DATE		DELIVERY MODE		
05/13/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doCKET@nutter.com

Office Action Summary

Application No.

09/955,680

Applicant(s)

O'NEIL, MICHAEL J.

Examiner

MARY HOFFMAN

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-26 is/are allowed.
- 6) ☒ Claim(s) 7, 9-11, 13-15, 17 is/are rejected.
- 7) ☒ Claim(s) 16 and 18-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-884)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Drawings

Upon further consideration of the drawings, the drawings are objected to because the drawings are difficult to read, For example, the numbers are handwritten, Figure 1 is a rough sketch, and Figure 2 is dark and some features are not visible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 19-21 are objected to because of the following informalities: It is noted that the claim 19 should state "A method for verifying," currently, the claim states "method for verifying" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7, 13 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Zdeblick et al. (U.S. 6,595,995).

Zdeblick et al. disclose a prosthesis alignment verification system, comprising an alignment verification device (see FIG. 17a) including a spacer element (see guide in FIG. 17a) having proximal and distal portions and a prosthesis engaging element (ref. #173,174) disposed on the distal portion; and an alignment guide surface (top part of ref. #171, e.g. at ref. #182) affixed to the spacer element and defining an alignment orifice (around ref. #180, 182), the alignment orifice being spaced apart from the prosthesis engaging element; and a spinal disc prosthesis (FIG. 17a, ref. #191) having an engaging element (see location where ref. #173,174 contact bone dowel ref. #191)

and a visual indicator element (surface of bone dowel ref. #191), the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced apart from the visual indicator element. The engagement of the alignment verification device with the prosthesis is adapted to permit, i.e. capable of permitting, a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element so that an image obtaining device is aligned with the prosthesis in a known orientation.

The spinal disc prosthesis incorporates an angle.

The system further comprising an orientable image obtaining device (laparoscope, ref. #170) including a sighting element for aiding in orienting the image obtaining device, the sighting device being aimable through the alignment orifice to the visual indicator element to provide a visual indication that the image obtaining device is oriented in a predetermined orientation with respect to the prosthesis.

Zdeblick et al. further disclose a method for verifying the orientation of an image obtaining device with respect to an implanted prosthesis, comprising the steps of: providing an alignment verification device including a spacer element having proximal and distal portions and a prosthesis engaging element disposed on the distal portion; and an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element; engaging the alignment verification device to the implanted prosthesis, the prosthesis having an engaging element and a visual indicator element, the engaging element

configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced apart from the visual indicator element; orienting the image obtaining device so that a sighting element on the image obtaining device is aimed through the alignment orifice to the visual indicator element to provide a visual indication that a predetermined orientation between the image obtaining device and the prosthesis has been achieved.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (U.S. 6,595,995) in view of Pasquet et al. (U.S. 6,716,245).

Zdeblick et al. disclose the claimed invention except for the prosthesis engaging element being generally rectangularly shaped and the engaging element of the prosthesis being a slot configured to engage the prosthesis engaging element, and the prosthesis engaging element including a depth stop element, and the spacer element including two elongate members with prosthesis engaging elements, and the prosthesis includes two engaging elements, each configured to engage one of the prosthesis engaging elements.

Pasquet et al. discloses a prosthesis engaging element being generally rectangularly shaped and the engaging element of the prosthesis being a slot configured to engage the prosthesis engaging element, and the prosthesis engaging element including a depth stop element, and the spacer element including two elongate members with prosthesis engaging elements, and the prosthesis includes two engaging elements, each configured to engage one of the prosthesis engaging elements (see FIG. 2) to provide a connection between an implant being inserted and the tool.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Zdebllick et al. with a prosthesis engaging element being generally rectangularly shaped and the engaging element of the prosthesis being a slot configured to engage the prosthesis engaging element, and the prosthesis engaging element including a depth stop element and , and the spacer element including two elongate members with prosthesis engaging elements, and the prosthesis includes two engaging elements, each configured to engage one of the prosthesis engaging elements in view of Pasquet et al. to provide a connection between an implant being inserted and the tool.

Claims 11 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdebllick et al. (U.S. 6,595,995) in view of Lin (U.S. Patent No. 6,569,168).

Zdebllick et al. disclose the claimed invention except for a prosthesis including two engaging elements and two opposed bone facing surfaces each having a slot as the engaging element and the spacer element comprising two elongate members each

having a prosthesis engaging element sized to engage a slot on the spinal disc prosthesis.

Lin discloses a prosthesis including two engaging elements and two opposed bone facing surfaces each having a slot as the engaging element and the spacer element comprising two elongate members each having a prosthesis engaging element sized to engage a slot on the spinal disc prosthesis to provide a connection between an implant being inserted and the tool.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Zdebllick et al. with a prosthesis including two engaging elements and two opposed bone facing surfaces each having a slot as the engaging element and the spacer element comprising two elongate members each having a prosthesis engaging element sized to engage a slot on the spinal disc prosthesis in view of Lin to provide a connection between an implant being inserted and the tool.

Allowable Subject Matter

Claims 16 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 19-21 are objected to as being dependent upon an objected base claim, but would be allowable if the objection was corrected.

Claims 22-26 are allowed.

Response to Arguments

Applicant's arguments, regarding the system claims, filed 01/26/2009 have been fully considered but they are not persuasive.

Due to the extended prosecution history in this case, it is noted that the examiner unsuccessfully attempted to contact Applicant's representative to discuss the cited prior art, which Applicant believes to be irrelevant. The examiner suggests that Applicant's representative contact the examiner by phone in order to set up a phone or personal interview to discuss the current rejections in order to come to agreement regarding the allowability of the claims.

Applicant states in the remarks that the cited art is irrelevant to the claimed invention. The examiner respectfully disagrees. Applicant's current system claims are directed to FIG. 2 of Applicant drawings. In FIG. 2, the invention appears to consist of a hollow guide with an aperture at the proximal end, and the hollow guide is attached (by prosthesis engaging elements) to a prosthesis (at engaging elements) so that the aperture is aligned with a proximal surface of the prosthesis to allow for a line of sight through the aperture to the prosthesis. The prior art cited, Zdeblick et al., (e.g. see FIG 17a) has the same structure as claimed, i.e. a hollow guide with an aperture attached to a prosthesis. It is noted that a fusion cage, which is best termed as an implant, can be considered a prosthesis, since the terms implant and prosthesis are often used interchangeably in the art. In addition, the examiner has clarified the above rejection to indicate how Zdeblick et al. anticipates the claimed invention, in particular, how the device of Zdeblick et al. is adapted to permit a sighting element of an image

obtaining device to be aligned with the alignment orifice and the visual indicator element so that an image obtaining device is aligned with the prosthesis in a known orientation.

The rejections are deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733